Carbopol 974P

Brand Name: BufferGel

Drug Description

Carbopol 974P is a high molecular weight, cross-linked, polyacrylic acid used as a gelling or tableting agent in many pharmaceuticals. [1] Carbopol 974P polymer is the major nonaqueous component (5% polymer, 94% water) of BufferGel. The additional constituents of BufferGel are dibasic potassium phosphate, magnesium sulfate, dibasic sodium phosphate, sorbic acid, monobasic sodium phosphate, and disodium EDTA. [2]

HIV/AIDS-Related Uses

Carbopol 974P is a polymer gel that maintains vaginal acidity, possibly impairing or preventing the transmission of HIV and other sexually transmitted infection (STI) pathogens. Carbopol 974P is formulated as a nonirritating vaginal lubricant called BufferGel. BufferGel is being investigated for the prevention of sexual transmission of HIV.[3]

Non-HIV/AIDS-Related Uses

Carbopol 974P may prevent the transmission of numerous STIs, including HSV-1 and HSV-2, Neisseria gonorrhoeae, Treponema pallidum, Haemophilus ducreyi, and a variety of bacteria associated with bacterial vaginosis. It is also under study as a spermicide to prevent pregnancy.

Carbopol 974P is formulated as a nonirritating vaginal lubricant called BufferGel. In a pilot study of 10 women, BufferGel was shown to be a moderately effective treatment for bacterial vaginosis.[4]

Pharmacology

Carbopol 974P is a negatively charged high molecular weight polymer, which is not absorbed and can neutralize twice its volume of base buffers, such as semen.[5] Carbopol 974P is formulated to buffer the concentration of free hydrogen ions at 0.1 mM, the level normally found in the vaginal lumen (pH 3.8-4.0). Hydrogen ions are buffered by the carboxyl groups that occur in large quantities on the carbopol 974P polymer.[6]

Carbopol 974P acidifies approximately twice its volume of semen to a pH of less than or equal to 5. In vitro, sperm and many STI pathogens are inactivated at a pH of less than 5. The pH for HIV inactivation has been reported between 4 and 5.8 in different studies.[7]

BufferGel is water-based and detergent free and has low osmotic activity. It contains no oil and is compatible with condoms and latex diaphragms.[8]

Adverse Events/Toxicity

Carbopol 974P formulated as BufferGel is not caustic, hypertonic, cell-permeant, or systemically absorbable.[9]

In a Phase I clinical trial, BufferGel showed minimal toxicity and was well tolerated, although two-thirds of the participants reported at least one mild or moderate adverse event. The most common adverse events were vaginal itching and irritation. Some symptoms disappeared within 1 hour after application of the product. Vaginal candidiasis and hyperkeratotic lesions required discontinuation of the product in a small percentage of trial participants.

An international Phase I clinical trial had similar results. Adverse events were categorized as mild to moderate and included candida on wet mount, vaginal/vulvar itching or burning after insertion or when passing urine, labial rash, lower abdominal pain, and vaginal discharge.

In both trials, adverse effects of BufferGel were generally self-limiting and resolved readily. Both trials reported a high degree of compliance and acceptability.[10] [11]

In a Phase I clinical trial of penile application of BufferGel, no serious adverse events or urethral inflammation were reported and adverse event rates were not significantly different from placebo.[12]

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Clinical Trials

For information on clinical trials that involve Carbopol 974P, visit the ClinicalTrials.gov web site at http://www.clinicaltrials.gov. In the Search box, enter: Carbopol 974P AND HIV Infections.

Dosing Information

Mode of Delivery: Intravaginal.[13]

Dosage Form: Topical gel.[14]

Storage: Store at room temperature.[15]

Chemistry

CAS Number: 151687-96-6[16]

Other Names

Carbopol 974P polymer[17]

Carbopol polymer[18]

Further Reading

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Turpin JA. Considerations and development of topical microbicides to inhibit the sexual transmission of HIV. Expert Opin Investig Drugs. 2002 Aug;11(8):1077-97.

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Manufacturer Information

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For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

• Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET

• Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET

References

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2. Protocol ID: HPTN 032 -

3. ReProtect LLC - Available at http://www.reprotect.com. Accessed 10/9/03.

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5. Natl Conf Women HIV - May 1997. Abstract 215.2.

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8. ReProtect LLC - Available at http://www.reprotect.com/. Accessed 10/9/03.

9. Protocol ID: CCN003 -

10. Clin Infect Dis - 2001 Feb 1;32(3):476-82.

11. J Acquir Immune Defic Syndr - 2001 Jan 1;26(1):21-7.

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